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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,516	08/15/2001	Katsumi Iga	074129-0488	9786

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EXAMINER	
GEORGE, KONATA M	
ART UNIT	**PAPER NUMBER**
1616	7

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/913,516	Applicant(s) IGA ET AL.	
	Examiner Konata M. George	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-40 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-40 are pending in this application.

Response to Election of Species

1. Claims 7 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on October 19, 2001 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim Objections

3. Claim 38 is objected to because of the following informalities: Claim 38 is missing a period at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 34-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph have been described in *In Re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) breadth of the claims; (6) the amount of direction of guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:
The invention provides for a method of preventing and/or treating angiotension II-mediated diseases by administrating a percutaneous absorption preparation containing an angiotension II antagonistic compound.

(2) The state of the prior art:
The prior art teaches use of angiotension II receptor antagonist useful in treating inflammatory conditions.

(4) The predictability or unpredictability of the art:
The predictability of the art is high for treating angiotension II mediated diseases. There are several patents and references with teach the use of angiotension II receptor antagonist in treating angiotension II-mediated diseases. The predictability of the art is low for preventing angiotension II-mediated diseases.

(6) The amount of direction or guidance presented:
The specification provides no guidance in the way of written description that demonstrates a method of preventing angiotension II-mediated diseases. No information is given to establish the regime for providing this prevention therapy.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The method of claims 38 and 39 is unclear. Claim 38 is drawn to a method of percutaneous absorption; however, the claim recites adding a compound to a preparation comprising a base and support. It is unclear how absorption occurs by just adding a compound to a support and base. Claim 39 is drawn to a method of regulating percutaneous absorption by adding a fatty acid ester, polyol and nonionic surfactant to preparation. For the same reasons above it is unclear how the method of regulating percutaneous occurs by simply adding other ingredients to the preparation.

7. Claim 40 provides for the use of a fatty acid ester, a polyol and a nonionic surfactant for regulating percutaneous absorption of a compound having angiotension II antagonistic activity, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim R jections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claim 40 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

9. Claim 40 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

10. For the purposes of advancing the prosecution of the application the examiner is interpreting claim 40 as a method of regulating percutaneous absorption comprising a fatty acid ester... antagonistic activity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 6, 8, 22, 29, 30 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by SmithKline Beecham Co. (WO 95/06410).

SmithKline Beecham Co. ('410) discloses the use of angiotension II receptor antagonist as a medicament for the treatment of chronic inflammatory diseases, which can be formulated for transdermal delivery as a patch or membrane (page 28, lines 2-7 and page 29, lines 14-17). Claim 13, page 41, lines 29-33; teach where the angiotension II receptor antagonist is 1-(cyclohexyloxycarbonyloxy) ethyl-2-ethoxy-1-[(2'-(1H-tetrazol-5-yl) biphenyl-4-yl) methyl]-benzimidazole-7-carboxylate or pharmaceutically acceptable salt.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-6, 8 and 10-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over SmithKline Beecham Co. (WO 95/06410) in view of Katz et al. (US Pat. No. 5,028,435).

SmithKline Beecham Co. ('410) discloses the use of angiotension II receptor antagonist as a medicament for the treatment of chronic inflammatory diseases, which can be formulated for transdermal delivery as a patch or membrane (page 28, lines 2-7 and page 29, lines 14-17). Claim 13, page 41, lines 29-33; teach where the angiotension II receptor antagonist is 1-(cyclohexyloxycarbonyloxy) ethyl-2-ethoxy-1-[(2'-(1H-tetrazol-5-yl) biphenyl-4-yl) methyl]-benzimidazole-7-carboxylate or

pharmaceutically acceptable salt. The prior art does not disclose the skin-contacting base (i.e. adhesive layer) containing the compound and a support (i.e. backing layer).

Katz discloses a system and method for transdermal drug delivery. The drug delivery system of Katz contains a matrix layer and a backing or enclosure (support) (col. 3, lines 58-62). Column 5, lines 43-55 teach exemplary drugs i.e. cardioactive drugs, anti-virals, analgesics, etc. which may be incorporated in the devise. Column 5, lines 56 through column 6, lines 1 and 2 teach the use of permeability enhancers such as fatty acid esters (i.e. isopropyl myristate), nonionic surfactants and fatty acid monoalkylamides and polyols (i.e. propylene glycol). It is the position of the examiner that permeability enhancers and permeability regulators are one in the same. Column 11, lines 55-60 describe the matrix containing an adhesive material which can be an acrylic.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the angiotension II receptor antagonist of '410 in the transdermal patch of Katz for the purpose of providing a percutaneous absorption preparation. The use of the angiotension II receptor antagonist in the invention of Katz is possible because Katz in column 5, lines 47-48 teaches that cardioactive drugs may be employed by the system. With respect to the claimed concentrations, the determination of particular concentrations and skin contacting area is within the skill of the ordinary worker as part of the process of normal optimization. The prior art discloses the same features in a percutaneous absorption preparation and yields the effects desired by the applicants. It is therefore the position of the examiner that the

concentrations of the fatty acid ester, polyol, nonionic surfactant and skin permeability regulator, do not provide any unusual and/or unexpected results.

Conclusion

13. Claims 1-6, 8 and 10-40 stand rejected.

14. Claims 7 and 9 are withdrawn for consideration as directed towards non-elected species.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached at (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George
Patent Examiner
Art Unit 1616